REMARKS

Claims 1-52, 69-77, 80-82, 84-92, and 96-99 are pending in the present application. Claims 80 and 96 have been amended and claims 83 and 94-95 have been cancelled without prejudice to or disclaimer of the subject matter contained therein. New claims 97-99 have been added and read upon the elected invention (i.e., methods of treating an autoimmune disease in a subject comprising administering an interferon antagonist) as well as the elected species (i.e., psoriasis as the autoimmune disease and antibody as the interferon antagonist). The amendments to claim 80 and the new claims are supported throughout the specification of the application as filed (e.g., at least at p. 17, lines 9-18, p. 43, line 5-p. 44, line 8 (Example 9), and page 29, line 7-page 33, line 7).

Claims 1-52, 69-77, 82, and 84 have been withdrawn. Because claims 82 and 84 depend from generic claim 80 that is believed to be allowable, Applicants respectfully request that claims 82 and 84 to the non-elected species be rejoined, examined, and allowed. See 37 C.F.R. § 1.141.

Applicants thank the Examiner for the helpful interview that was conducted on March 29, 2007 with the undersigned.

Reexamination of the application and reconsideration of the rejections are respectfully requested in view of the above amendments and the following remarks, which follow the order set forth in the Office Action.

Claim rejections—35 U.S.C. § 102

Claims 80-82, 85-92, and 94-96 were rejected under 35 U.S.C. § 102 as being anticipated by Skurkovich et al. (U.S. Patent No. 5,888,511). This rejection is traversed for the reasons that follow.

In order to advance prosecution, and without acquiescence to the rejection, claim 80 has been amended to recite a method for treating an autoimmune disease comprising administering to the subject a therapeutically effective amount of a composition **consisting of**:

one or more humanized or human monoclonal anti-IFN-α antibodies or antigen-binding fragments thereof and

a diluent, a preservative, a solubilizer, an emulsifier, an adjuvant, a carrier, a buffer, a pharmaceutical additive, a detergent, an anti-oxidant, a bulking substance, a tonicity modifier, a flavoring agent, a lubricant, a suspending agent, a filler, a glidant, a compression aid, a binder, a tablet-disintegrating agent, an encapsulating material, a sweetener, a thickening agent, a color, a viscosity regulator, a stabilizer,

> an osmo-regulator, a pharmaceutically acceptable propellent, a flavorant, a dye, a coating, or a combination of any thereof.

Claim 80 has also been amended to recite that **no neutralizing anti-TNF antibodies are used in the method**, thus excluding the use of anti-TNF antibodies in the method. Support for this amendment is found at least in Example 9 of the specification as filed (p. 43, line 5-p. 44, line 8). Claim 80 also recites that the autoimmune disease is not rheumatoid arthritis, AIDS, or diabetes.

New claim 99 recites a method for treating an autoimmune disease **consisting of** administering to the subject a therapeutically effective amount of a composition **consisting of** one or more humanized or human monoclonal anti-IFN-α antibodies or antigen-binding fragments thereof and one or more of the other recited components (diluent, preservative, etc.), wherein the autoimmune disease is not rheumatoid arthritis, AIDS, or diabetes.

Skurkovich et al. does not disclose effective treatment methods comprising the administration of a composition consisting of humanized or human monoclonal antibodies (or antigen-binding fragments thereof) against IFN-α alone (i.e., as the sole active ingredient) for the autoimmune diseases encompassed by claim 80, wherein no neutralizing anti-TNF antibodies are used in the method. Skurkovich et al. only discloses alleged treatments comprising administration of antibodies against a single cytokine (such as IFN-α) as the sole active ingredient of a composition that is administered in the context of rheumatoid arthritis and AIDS (see, e.g., *Column 3, line 57-column 4, line 9 of Skurkovich et al.*) and in conjunction with extracorporeal treatment comprising "passing fluid [from a patient] over **anti-TNF antibodies** ..." (see, e.g., *Column 6, lines 16-35 of Skurkovich et al. (emphasis added)*). In fact, Skurkovich et al. teaches that multiple therapeutic agents are **required** to effectively treat autoimmune diseases:

> ... because autoimmune diseases are complex, often characterized by multiple cytokine abnormalities, **effective treatment** appears to **require** the **simultaneous administration or utilization of several agents**, each targeting a specific cytokine pathway or its by-product. To meet this need, the methods of treatment of the present invention include not only the use of specific antibodies,. [sic] but also provide pleiotrophic autoimmune inhibitors, including antibodies to cytokines and HLA class II antigens, and antigens for the removal of autoantibodies to target cells or DNA. The use of these antibodies and antigens as disclosed in the present invention results in the removal, neutralization or inhibition of the pathogenic cytokine(s), HLA class II antigens, and/or

autoantibody(ies) to target cells or DNA from the autoimmune patient, thereby significantly improving the quality of life of the individual.

Column 4, lines 9-24 (emphasis added).

To anticipate a claim, the reference must teach every element of the claim. *MPEP § 2133.*

Claim 80 is not anticipated because Skurkovich et al. does not teach treating an autoimmune disease that is not rheumatoid arthritis, AIDS, or diabetes using a method comprising administering a therapeutically effective amount of a composition **consisting of one or more humanized or human monoclonal anti-IFN-α antibodies or antigen-binding fragments thereof** and one or more of the other recited components, **wherein no neutralizing anti-TNF antibodies are used in the method**. In addition, new claim 99 is not anticipated because Skurkovich et al. does not teach treating an autoimmune disease that is not rheumatoid arthritis, AIDS, or diabetes using a method **consisting of** administering a therapeutically effective amount of a composition **consisting of one or more humanized, monoclonal anti-IFN-α antibodies or antigen-binding fragments thereof** and the one or more of the other recited components.

Therefore, because all of the limitations of claim 80 are not taught in Skurkovich et al., claim 80 and claims 81-82, 84-92, and 96-98 depending therefrom are not anticipated, and Applicants respectfully request that the rejection be withdrawn.

Conclusion

For the foregoing reasons, claims 80-82, 84-92, and 96-99 are considered allowable. A Notice to this effect is respectfully requested. If any questions remain, the Examiner is invited to contact the undersigned at the number given below.

Respectfully submitted,

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I hereby certify that the application/correspondence attached hereto is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR § 1.10 on the date indicated above and is addressed to the Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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